

REMARKS

Claims 1-4 are all the claims pending in the application; each of the claims has been rejected.

Claims 1-4 have been cancelled. New claims 5-16 have been added.

Support for the method of identifying a test substance which modulates human G-protein coupling receptor-like protein (CRTH2) activity recited in claim 5 can be found at page 15, line 18, through page 16, line 17; at page 16, line 22, through page 17, line 17; and in Examples 3 and 4.

Claim 6 finds support at page 13, lines 11-25.

Claim 7 finds support in Example 3 (pages 21-22), specifically at page 22, lines 2-4.

Claims 8 and 9 find support at page 6, lines 8-13.

Claim 10 finds support at page 13, lines 21-22; page 15, lines 18-23.

Claim 11 finds support at page 13, lines 23-24.

Claim 12 finds support at page 17, lines 1-8.

Claims 13 and 14 find support at page 17, lines 8-10.

Claim 15 finds support at page 15, lines 9-11.

Claim 16 finds support at page 17, line 23, through page 18, line 5.

The specification and Figure 4 have been amended to correct an obvious misspelling.

No new matter has been added. Entry of the amendment is respectfully requested.

I. Comments on Re-dated Office Action

Applicants note that a Non-Final Office Action was issued in the instant application on November 12, 2003.

A second, Non-Final Office Action was issued on January 8, 2004. At the top of page 2 of the second Action, the Examiner states that as a Preliminary Amendment filed November 12, 2003, was received in the U.S. PTO on the same day that the first Action was mailed, the first action was being vacated in favor of the second Action.

In a telephone conference with the Examiner on January 22, 2004, Applicants noted that a Preliminary Amendment was not filed in this application on November 12, 2003. The Examiner reviewed the matter and found that the Preliminary Amendment submitted by Applicants on February 22, 2002, had been mistakenly dated November 12, 2003, by the U.S. PTO when the electronic file wrapper was prepared. The Examiner also noted that the first page of the Appendix was missing from the electronic version of the Amendment prepared by the U.S. PTO.

The Examiner requested Applicants to provide a complete copy of the Preliminary Amendment filed February 22, 2002, with the instant response to the outstanding Office Action. As requested, Applicants include a complete copy of the Amendment herewith.

II. Priority Data

At paragraph 2 of the Office Action, the Examiner states that the specification is objected to because the priority data (reference to PCT/JP00/05615) is not recited in the first line of the specification.

In response, Applicants respectfully note that as the instant application is the national stage application of international application number PCT/JP00/05615, it is considered to be the same application as the international application and therefore no reference needs to be made to the national stage application (*please see* MPEP §1893.03(c)).

However, to further prosecution of the application, Applicants include herewith an amendment to the specification as requested by the Examiner.

III. Rejection of Claims Under 35 U.S.C. §112

A. At paragraph 3 of the Office Action, claims 1-4 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner states that while the specification provides enablement for a method of identifying ligands which bind to the CRTH2 and PGD receptors, or which modulate intracellular calcium, it does not reasonably provide enablement for any and all “properties” of a test compound or for all “effects” on CRTH2 and PGD receptors, or for “derivatives.”

B. At paragraph 4 of the Office Action, claims 1-4 are rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description.

The Examiner explains that the pending claims are genus claims, and that Applicants have not provided adequate written description for any and all “properties” of a test compound or for all “effects” on CRTH2 and PGD receptors, or for “derivatives” of CRTH2 receptors. The Examiner also states that because the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, “properties,” “effects” and “derivatives” alone are insufficient to describe the genus. The Examiner concludes that one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus.

C. At paragraph 5 of the Office Action, claims 1-4 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

(1) The Examiner states that claims 1-4 are incomplete for omitting essential steps, such omission amounting to a gap between steps. The Examiner explains that the omitted step is a conclusion step to identify when the method has been completed. The Examiner also finds the “property” of the test substance and the “effect” on CRTH2 and PGD to be unclear.

(2) Claims 1-4 are said to be confusing because it is unclear whether “CRTH2” is referring to the receptor or to the cell itself.

(3) Claims 2-4 are said to be confusing because these claims only define an assay for one of the receptors. The Examiner also states that it is not clear what “function” of the other receptor in each of these claims is being measured.

(4) Claim 3 is said to be confusing because it is not clear to what “derivative thereof” is referring.

Applicants’ response

In response, Applicants note that included in the instant Amendment is the cancellation of claims 1-4. In view of the cancellation of claims 1-4, each of the rejections under 35 U.S.C. §112, is moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants also note that new claims 5-16 have been added. New claims 5-16 have been drafted with careful consideration of the points raised by the Examiner in the §112 rejections of the claims. Thus, a small genus of molecules, with specifically and clearly recited characteristics, is now being claimed.

Applicants also provide the following brief comments so that the subject matter disclosed and claimed in the instant application is more clearly understood.

PGD₂ is a member of the prostanoid family, members of which are known to have a variety of effects in living organisms, such as a human being. The effects of PGD₂ observed are, at least in some cases, rather contrary to each other. For example, either contraction or relaxation can be triggered in human uterus smooth muscle by PGD₂ (*see* page 3 of the specification). Such evidence suggests that the effects of PGD₂ are mediated through two different subtypes of PGD₂ receptors.

Prior to the present application, only one PGD₂ receptor was known, namely human prostaglandin D receptor (the DP receptor). As disclosed in the instant application, Applicants have now identified CRTH2 as a second PGD₂ receptor. As shown in the Examples of the instant application, PGD₂ induces different effects through the two receptors.

Based on these novel findings, Applicants now provide methods for screening test substances for their ability to modulate the effects of PGD₂ on CRTH2.

IV. Rejection of Claims Under 35 U.S.C. §103

At paragraph 6 of the Office Action, claims 1-4 are rejected under 35 U.S.C. §103(a) as being unpatentable over Li et al. (US patent publication 2002/0022218).

In response, Applicants note that Li et al. was published February 21, 2002, and is the publication of an application claiming priority back to a U.S. provisional application filed July 7, 2000.

The instant application claims priority to two Japanese applications: Japanese Application No. 11-236207, filed August 23, 1999, and Japanese Application No. 2000-153172, filed May 24, 2000. Both of the priority applications were filed prior to the earliest effective filing date of the Li et al. publication.

Applicants enclose herewith sworn translations into English of the two Japanese priority documents, thus perfecting priority of the instant application. Each of the new claims in the instant amendment is fully supported by one or both of the priority documents.

As the earliest priority date of Li et al. is after the filing date of the two priority applications, Li et al. may not serve as legally-effective prior art against any of the claims of the instant application under any paragraph of 35 U.S.C. §102. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

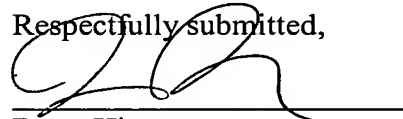
SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Respectfully submitted,



Drew Hissong
Registration No. 44,765

Date: April 13, 2004